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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,384	08/29/2008	Ajit Lalvani	HO-P03388US0	7392
26271 7590 08/25/2011 FULBRIGHT & JAWORSKI, LLP 1301 MCKINNEY SUITE 5100 HOUSTON, TX 77010-3095			EXAMINER SWARTZ, RODNEY P	
			ART UNIT 1645	PAPER NUMBER
			NOTIFICATION DATE 08/25/2011	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### **DETAILED ACTION**

1. Applicant's Response to Office Action, received 12 August 2011, is acknowledged.

Claims 2, 6, 8 and 21 have been amended.

2. Claims 2-13 and 15-23 are pending and under consideration.

### **Rejections Withdrawn**

3. The rejection of claim 8 under 35 U.S.C. 112, second paragraph, is withdrawn in light of the claim amendment.

4. The rejection of claims 2-13 and 15-20 under 35 U.S.C. 112, second paragraph, is withdrawn in light of the claim amendments.

5. The rejection of claims 21 and 23 under 35 U.S.C. 112, first paragraph, is withdrawn in light of the claim amendments.

### **Rejections Maintained**

6. The rejection of claim 22 under 35 U.S.C. 112, second paragraph, is maintained for reasons of record.

Applicant argues that claim 22 is now cancelled.

The examiner has considered applicant's argument, but does not find it persuasive because the claim listing continues to show the status of claim 22 as "Original" and not rejected.

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.



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7. Claims 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

The omitted steps are: correlating the comparison in step iii to determination of the stage of a *M. tuberculosis* infection.

As newly amended, claim 21 is now drawn to a method of ascertaining the stage of a *M. tuberculosis* infection by determining whether there is a differential T cell response to different *M. tuberculosis* antigens comprising: (i) determining T-cell response to  $\geq 1$  of Rv3879c, Rv3873, Rv3878, and Rv1989c; (ii) determining the T-cell response to  $\geq 1$  of ESAT-6 and CFP-10; and (iii) comparing the response in (i) and (ii).

However, there is no step which actually correlates the differential response to the stage, i.e., an increase in (i) over (ii), or a decrease in (i) over (ii) and to what level.

Claims 22 and 23 depend from claim 21, but do not correct the omission of steps.

### **Double Patenting**

8. Applicant is advised that should claim 21 be found allowable, claim 22 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

As newly amended, claim 21 is now drawn to a method of ascertaining the stage of a *M. tuberculosis* infection by determining whether there is a differential T cell response to different *M. tuberculosis* antigens comprising: (i) determining T-cell response to  $\geq 1$  of Rv3879c, Rv3873,



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Rv3878, and Rv1989c; (ii) determining the T-cell response to  $\geq 1$  of ESAT-6 and CFP-10; and (iii) comparing the response in (i) and (ii).

Claim 22 is the method according to claim 21 wherein T cell responses to  $\geq 1$  of Rv3879c, ESAT-6, CFP10, Rv3873, Rv3878, Rv1989c are measured. These are the identical antigens as listed in claim 21.

### Conclusion

9. Claims 21-23 are rejected.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday-Thursday from 7:30 AM to 6:00 PM EST. If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Gary Nickol, at (571)272-0835. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Information



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regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P Swartz/

Primary Examiner, Art Unit 1645

August 24, 2011